file copy

Interview Summary	Application No.	Applicant(s)	
	09/533,906	COLLINS ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Diana Johannsen*. (3)_____.

(2) *Jean Fordis*. (4)_____.

Date of Interview: *15 April 2002* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____ .

Claim(s) discussed: *all pending* .

Identification of prior art discussed: *NA* .

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Attachment* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Diana B Johannsen 4/15/02
Examiner's signature, if required

DBJ 36 4/19/02

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1 111, 1 135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing
All business with the Patent or Trademark Office should be transacted in writing The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Attachment to Interview Summary

On 4/10/02, several issues were briefly discussed. Applicants' representative inquired as to whether it would be possible to pick up the Notice of Allowability (rather than have it mailed) in order to facilitate prompt receipt of the Notice and payment of the issue fee. The examiner noted that she would consult with her supervisor regarding this possibility. Ms. Fordis also proposed that applicant file a paper making the amendments agreed to at the personal interview of 4/2/02 (in lieu of the previously discussed Examiner's amendment), as this would permit applicant to file the amendments at the same time as the required Supplemental Oath/Declaration. It was agreed that applicant would file the amendment; however, the examiner proposed that applicants' representative first provide a draft for the examiner's review, as any further changes made by a subsequent Examiner's amendment would be likely to necessitate another supplemental Oath/Declaration. It was agreed that applicants' representative would provide a draft Amendment to the examiner by FAX. It was further agreed that this draft Amendment, as well as the draft proposal provided by the examiner to applicants' representative by FAX on 3/28/02 and the draft claims and draft proposals provided by applicants' representative to the examiner at the personal interview of 4/2/02, would be attached hereto. The draft Amendment was FAXed to the examiner on the evening of 4/10/02 and discussed by phone on 4/11/02. The examiner noted the absence of "a" prior to the recitation of "reagent" in line 3 of claim 28. The examiner also noted that because the instructions provided in paper no. 32 with respect to claim 44 were ambiguous (specifically, because the amendment attempted to both cancel and

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amend the claim), no amendments to claim 44 had been entered, and applicants' representative could instruct the examiner as to whether the claim should be canceled or amended. Ms. Fordis indicated that she preferred to amend claims 44-45 as discussed at the personal interview of 4/2/02, and this was agreed to. The examiner noted that if applicants had filed or still intended to file a divisional of the instant application, a reference to that divisional application would be required in the present application (and vice versa), as discussed in MPEP 1451. Ms. Fordis noted that a divisional has not yet been filed, but that she would review MPEP 1451 regarding this matter. On 4/15/02, the examiner contacted Ms. Fordis to inform her that the Notice of Allowability could be picked up rather than mailed. The examiner will contact Ms. Fordis to arrange for pick up after the allowance is complete.

The following papers are attached hereto:

1) draft amendment proposed by the examiner on 3/28/02, labeled "Appendix A;"

2) draft set of claims and draft proposals provided by applicants' representative at the personal interview of 4/2/02, labeled "Appendix B;" and

3) draft amendment provided to the examiner by FAX on 4/10/02, labeled "Appendix C."

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	3924
CONNECTION TEL	912024084400
SUBADDRESS	
CONNECTION ID	
ST. TIME	04/15 08:58
USAGE T	02'43
PGS.	5
RESULT	OK

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Fax Cover Sheet

Date: 15 Apr 2002

To: Jean Fordis	**From:** Diana Johannsen
Application/Control Number: 09/533,906	**Art Unit:** 1634
Fax No.: 202/408-4400	**Phone No.:** 703/305-0761
Voice No.: (202) 408-4016	**Return Fax No.:** 703/872-9306
Re:	**CC:**

☐ **Urgent** ☐ **For Review** ☐ **For Comment** ☐ **For Reply** ☐ **Per Your Request**

Comments:
Interview Summary; attachments not included.

Jean - I just left a message re: pick up of Notice of All. at your DC number.

Diana

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Diana

9 40 am

Number of pages 5 **including this page**

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To:	**Name:**	Jean Fordis
	Company:	
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37 C.F.R. 1.6 sets forth the types of correspondence that can be communicated to the Patent and Trademark Office via facsimile transmissions. Applicants are advised to use the certificate of facsimile transmission procedures when submitting a reply to a non-final or final Office action by facsimile (37 CFR 1.8(a)).

Fax Notes:

Draft amendment.

Date and time of transmission: Thursday, March 28, 2002 3:39:42 PM
Number of pages including this cover sheet: 05

Appendix A

DRAFT AMENDMENT

Cancel claims 20-26, 65, 67-69, 72 and 76-82.

Amend the claims as follows:

In claim 1, line 4, after "from the sample" insert--, thereby producing a separated target polynucleotide--.

In claim 1, line 6, after "separated target polynucleotide" insert--of (b)--.

In claim 4, lines 1-2, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase--.

In claim 6, line 1, before "target polynucleotide" insert--separated--.

In claim 7, line 5, after "sample" insert--, thereby producing a separated target polynucleotide--.

In claim 7, line 6, after "separated target polynucleotide" insert--of (b), thereby producing an amplified target polynucleotide--.

In claim 7, line 7, after "amplified target polynucleotide" insert--of (c)--.

In claim 10, lines 1-2, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase--.

In claim 12, line 1, before "target polynucleotide" insert--separated--.

In claim 17, lines 1-2, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase--.

In claim 18, line 1, before "target polynucleotide" insert--separated--.

In claim 19, line 5, after "sample" insert--, thereby producing a separated target polynucleotide--.

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In claim 19, line 6, after "separated target polynucleotide" insert--of (b)--.

In claim 19, line 7, after "polymerase" insert--, thereby producing an amplified target polynucleotide--.

In claim 19, line 8, after "amplified target polynucleotide" insert--of (c)--.

In claim 27, line 3, before "reagent" insert--a--.

In claim 27, line 12, after "the target polynucleotide" insert--in the probe-target complex--.

In claim 28, line 3, before "reagent" insert--a--.

In claim 28, line 12, after "the target polynucleotide" insert--in the probe-target complex--.

In claim 29, lines 2-3, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase--.

In claim 32, lines 2-3, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase--.

In claim 34, line 9, after "target polynucleotide" insert--of (c)--.

In claim 35, lines 2-3, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase--.

In claim 38, line 9, after "target polynucleotide" insert--of (c)--.

In claim 38, line 11, after "second medium" insert--, thereby producing an amplified target polynucleotide--.

In claim 39, lines 2-3, delete "the target polynucleotide is amplified with a polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase--.

In claim 42, line 1, delete "the amplification" and insert therefore--said amplifying *in*

vitro--.

In claim 43, line 1, delete "the amplification" and insert therefore--said amplifying *in vitro*--.

In claim 44, line 1, before "target polynucleotide" insert--separated--.

In claim 45, line 1, delete "the amplification" and insert therefore--said amplifying *in vitro*--.

In claim 46, lines 1-2, delete "the target polynucleotide is amplified with more than one polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase--.

In claim 48, line 1, delete "the amplification" and insert therefore--said amplifying *in vitro*--.

In claim 49, line 1, delete "the amplification" and insert therefore--said amplifying *in vitro*--.

In claim 50, line 1, before "target polynucleotide" insert--separated--.

In claim 51, line 1, delete "the amplification" and insert therefore--said amplifying *in vitro*--.

In claim 52, lines 1-2, delete "the target polynucleotide is amplified with more than one polymerase" and insert therefore--said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase--.

In claim 64, line 1, after "wherein" insert--said amplifying *in vitro* comprises amplifying--.

In claim 64, line 1, delete "is amplified".

In claim 66, line 1, after "wherein" insert--said amplifying *in vitro* comprises amplifying--.

In claim 66, line 1, delete "is amplified".

In claim 71, line 1, after "wherein" insert--said amplifying *in vitro* comprises amplifying--.

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In claim 71, line 1, delete "is amplified".

In claim 73, line 1, delete "72" and insert therefore--71--.

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We claim:

1. (Amended) A method for amplifying a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the support and bound target polynucleotide from the sample thereby producing a separated target polyneucleotide; and

(c) amplifying *in vitro* the separated target polynucleotide of (b).

2. The method of claim 1 wherein the first support is retrievable.

3. The method of claim 1 wherein the first support includes a probe which binds with the target polynucleotide.

4. (Amended) The method of claim 1 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

5. (Amended) The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Q replicase].

6. (Amended) The method of claim 4 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

7. (Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the target separated polynucleotide of (b), thereby producing an amplified

Appendix B

target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.

8. The method of claim 7 wherein the first support is retrievable.

9. The method of claim 8 wherein the first support includes a probe which binds with the target polynucleotide.

10. (Amended) The method of claim 7 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

11. (Amended) The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

12. (Amended) The method of claim 11 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

13. (Amended) The method of claim 7 wherein the amplified target polynucleotide is contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. (Amended) The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

15. The method of claim 7 wherein the amplified target polynucleotide is contacted with a second support which binds to the amplified target polynucleotide.

16. (Amended) The method of claim 15 wherein the [amplified target polynucleotide is contacted with] second support includes a labeled probe, and the presence of the target

polynucleotide in the sample is indicated by detection of said label.

17. (Amended) The method of claim 16 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

18. (Amended) The method of claim 17 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

19. (Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the [sample] separated target polynucleotide of (b) with a DNA polymerase, thereby producing an amplified target polynucleotide;

(d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucletide; and

(e) detecting the presence of [the amplified target polynucleotide] labeled probe as indicative of the presence of the target polynucleotide in said sample.

delete 20. A kit for detecting a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample;

(b) means for amplifying the target polynucleotide;

(c) means for binding the amplified target polynucleotide to a solid support; and

(d) means for labeling the amplified target polynucleotide.

delete 21. The kit of claim 20 wherein:

(a) the means for substantially separating the target polynucleotide from the sample include a first support;

(b) the means for amplifying the target polynucleotide include a polymerase;

(c) the means for binding that amplified target polynucleotide to a solid support include a capture probe which binds to the solid support and to the amplified target polynucleotide; and

(d) a detector probe for labeling the amplified target polynucleotide.

delete 22. The kit of claim 21 further comprising a capture probe which binds to the first support and to the target.

delete 23. The kit of claim 22 wherein the polymerase is a DNA polymerase and the detector probe is labeled.

delete 24. A kit for amplifying a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample and

(b) means for amplifying the target polynucleotide.

delete 25. The kit of claim 24 wherein:

(a) the means for substantially separating the target polynucleotide from the sample includes a support which binds to the target polynucleotide and

(b) the means for amplifying the target polynucleotide includes a polymerase.

delete 26. The kit of claim 25 wherein:

(a) the polymerase is a DNA polymerase; and

(b) the means for substantially separating the target polynucleotide from the sample includes a probe which binds to the target polynucleotide and the support.

27. (Amended) A method for amplifying a target polynucleotide contained in a sample

medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium.

28. (Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

29. (Amended) The method of detecting a target polynucleotide of claim 28 wherein wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

30. (Amended) The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase[, or Q[illegible] replicase].

31. The method for detecting a target polynucleotide of claim 30 wherein the polymerase is a DNA polymerase.

32. (Amended) The method for amplifying a target polynucleotide of claim 27 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

33. The method for amplifying a target polynucleotide of claim 32 wherein the polymerase is a DNA polymerase.

34. (Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe from the second medium; and

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. (Amended) The method for amplifying a target polynucleotide of claim 34 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

36. (Amended) The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Q replicase].

37. The method for amplifying a target polynucleotide of claim 36 wherein the polymerase is a DNA polymerase.

38. (Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of c into the second medium;

(e) substantially separating the support and bound probe form the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium, thereby producing an amplified target polynucleotide; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucletide in said sample.

39. (Amended) The method for detecting a target polynucleotide of claim 38 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

40. The method for detecting a target polynucleotide of claim 39 wherein the polymerase is a DNA polymerase.

41. The method for amplifying a target polynucleotide of claim 1 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

42. (Amended) The amplification method of claim [41] 1 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

43. (Amended) The amplification method of claim 42 wherein [the amplification] said amplifying *in vitro* is exponential.

44. (Amended) The amplification method of claim [41] 1 wherein the separated target polynucleotide is amplified with a polymerase and at least one oligonucleotide primer.

45. (Amended) The amplification method of claim 44 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

46. (Amended) The amplification method of claim [41] 1 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

47. The method for detecting a target polynucleotide of claim 7 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

48. (Amended) The detection method of claim [47] 7 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

49. (Amended) The detection method of claim 48 wherein [the amplification] said amplifying *in vitro* is exponential.

50. (Amended) The detection method of claim [47] 7 wherein the separated target polynucleotide is amplified with a polymerase and at least one oligonucleotide primer.

51. (Amended) The detection method of claim 50 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

52. (Amended) The detection method of claim [47] 7 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

53. The method for detecting a target polynucleotide of claim 19 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

delete?? 54. The detection kit of claim 20 wherein the means for amplifying provide for *in vitro* amplification of the target polynucleotide to produce a multitude of polynucleotide amplification products.

delete?? 55. The amplification kit of claim 24 wherein the means for amplifying provide for *in vitro* amplification of the target polynucleotide to produce a multitude of polynucleotide amplification products.

56. The method for amplifying a target polynucleotide of claim 27 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

57. The method for detecting a target polynucleotide of claim 28 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

58. The method for amplifying a target polynucleotide of claim 34 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

59. The method for detecting a target polynucleotide of claim 38 wherein the target polynucleotide is amplified *in vitro* to produce a multitude of polynucleotide amplification products.

delete 60. The exponential amplification of claim 43 wherein the target polynucleotide is amplified with random primers.

delete 61. The exponential amplification of claim 43 wherein the target polynucleotide is amplified with specially tailored primers.

delete 62. The exponential amplification of claim 49 wherein the target polynucleotide is amplified with random primers.

delete 63. The exponential amplification of claim 49 wherein the target polynucleotide is amplified with specially tailored primers.

64. (Amended) The method of claim 1 wherein <u>said amplifying *in vitro* comprises amplifying</u> the separated target polynucleotide [is amplified] non-specifically with random primers.

delete 65. The method of claim 1 wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

66. (Amended) The method of claim 7 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] non-specifically with random primers.

delete 67. The method of claim 7 wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

delete 68. The amplification kit of claim 25 wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide non-specifically with random primers.

delete 69. The amplification kit of claim 25 wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide specifically with specially tailored primers.

70. The method of claim 9 wherein the probe first binds with the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

71. (Amended) The method of claim 70 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] non-specifically with random primers.

delete 72. The method of claim 70 wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

73. (Amended) The method of claim [72] 71 wherein the sample is a clinical sample.

74. The method of claim 73 wherein the probe comprises a nucleotide sequence specific to a complementary nucleotide sequence in the target polynucleotide and a homopolymeric tail sequence.

75. The method of claim 74 wherein the support comprises a homopolymeric tail complementary to the homopolymeric tail of the probe.

delete 76. A kit for detecting a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample prior to amplification of the target polynucleotide;

(b) means for amplifying *in vitro* the separated target polynucleotide; and

(c) means for detecting the presence of the amplified target polynucleotide as indicative of the presence of the target polynucleotide in the sample.

delete 77. The detection kit of claim 76 wherein:

(a) the means for substantially separating the target polynucleotide from the sample include a first support and a probe that binds to both the first support and the target polynucleotide;

(b) the means for amplifying *in vitro* the separated target polynucleotide include a polymerase; and

(c) the means for detecting the presence of the amplified target polynucleotide include a detector probe.

delete 78. The detection kit of claim 77 wherein the means for substantially separating the target polynucleotide from the sample includes a first support that binds to the target polynucleotide via a probe.

delete 79. The detection kit of claim 78 wherein the means for substantially separating the target polynucleotide from the sample include a probe that first binds to the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

delete 80. The detection kit of claim 79 wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide non-specifically with random primers.

delete 81. The detection kit of claim 79 wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide specifically with specially tailored primers.

delete 82. The detection kit of claim 81 wherein the sample is a clinical sample.

09533906.071601

Proposed amendments to claims 44 and 50

44. (Twice amended) The amplification method of claim [41] 1 wherein the separated target polynucleotide is amplified with [a polymerase and] at least one oligonucleotide primer.

50. (Twice amended) The detection method of claim [47] 7 wherein the separated target polynucleotide is amplified with [a polymerase and] at least one oligonucleotide primer.

****

44. The amplification method of claim 1 wherein ~~the separated target polynucleo~~tide is amplified with at least one oligonucleotide primer.

50. The detection method of claim 7 wherein the separated target polynucleotide is amplified with at least one oligonucleotide primer.

Proposed amendments to claims 64, 66, 71

64. (Twice amended) The method of claim 1 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] non-specifically [with random primers].

66. (Twice amended) The method of claim 7 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] non-specifically [with random primers].

71. (Twice amended) The method of claim 70 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] non-specifically [with random primers].

73. (Twice amended) The method of claim **70** [72] 71 wherein the sample is a clinical sample.

****

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide non-specifically.

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide non-specifically.

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide non-specifically.

73. The method of claim 70 the sample is a clinical sample.

Proposed amendments to proposed deleted claims 65, 67, and 72 (to recite only specially tailored primers)

65. (Twice amended) The method of claim 1 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] [specifically] with specially tailored primers.

67. (Twice amended) The method of claim 7 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] [specifically] with specially tailored primers.

72. (Twice amended) The method of claim 70 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide [is amplified] [specifically] with specially tailored primers.

73. (Twice mended) The method of claim **72** [72] 71 wherein the sample is a clinical sample.

****

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide with specially tailored primers.

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide with specially tailored primers.

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying the separated target polynucleotide with specially tailored primers.

73. The method of claim 72 wherein the sample is a clinical sample.

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FACSIMILE TRANSMITTAL

TO	FROM
Name: Examiner Diana B. Johannsen	**Name:** Jean B. Fordis
Firm: USPTO	**Phone No.:** 650-849-6607
Fax No.: 703-746-5064	**Fax # Verified by:** jbf
Phone No.: 703-305-0761	**# Pages (incl. this):** 19
Subject: Reissue Appln of Collins et al.	**Date:** April 10, 2002
Your File No.: Appln No. 09/533,906	**Our File No.:** 01147-0142

Confirmation Copy to Follow: [redacted]-No

Message:

Per our discussion on the telephone today, we attach a draft Amendment for your consideration.

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Appendix C

DRAFT

PATENT
Customer Number 22,852
Attorney Docket No. 1147-0142

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of: U.S. Patent No. 5,750,338	)	
Mark L. Collins et al.	)	Group Art Unit: 1655
Reissue Serial No.: 09/533,906	)	Examiner: D. Johannsen
Reissue Application Filed: March 8, 2000	)	
For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS	)	

REISSUE LITIGATION BOX
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

SUPPLEMENTAL AMENDMENT

Further to the Amendment submitted on March 8, 2002, the draft proposed Examiner's Amendment forwarded by facsimile on March 28, 2002, the Interview of April 2, 2002, and the Interview Summary forwarded by facsimile on April 3, 2002 (but not yet mailed), the Patent Owner requests that the application be amended as follows:

IN THE CLAIMS

In the originally issued claims 1-40, please cancel claims 20-26 without prejudice. Please amend original claims 1, 4-7, 10-14, 16-19, 27-30, 32, 34-36, and 38-39 as follows:

1. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

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(b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and

(c) amplifying *in vitro* the separated target polynucleotide of (b).

4. (Amended) The method of claim 1 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

5. (Amended) The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

6. (Amended) The method of claim 4 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

7. (Twice Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the separated target polynucleotide of (b), thereby producing an amplified target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.

10. (Amended) The method of claim 7 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

11. (Amended) The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

12. (Amended) The method of claim 11 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

13. (Amended) The method of claim 7 wherein the amplified target polynucleotide is

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contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. (Amended) The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

16. (Amended) The method of claim 15 wherein the [amplified target polynucleotide is contacted with] second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

17. (Amended) The method of claim 16 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

18. (Amended) The method of claim 17 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

19. (Three-times Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the [sample] separated target polynucleotide of (b) with a DNA polymerase, thereby producing an amplified target polynucleotide;

(d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and

(e) detecting the presence of [the amplified target polynucleotide] the labeled probe as indicative of the presence of the target polynucleotide in said sample.

27. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

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(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium.

28. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

29. (Amended) The method of detecting a target polynucleotide of claim 28 wherein [the

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target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

30. (Amended) The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase[, or Qβ replicase].

32. (Amended) The method for amplifying a target polynucleotide of claim 27 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

34. (Twice Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe from the second medium; and

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. (Twice Amended) The method for amplifying a target polynucleotide of claim 34 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

36. (Amended) The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

38. (Twice Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the

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sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe form the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium, thereby producing an amplified target polynucleotide; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucletide in said sample.

39. (Amended) The method for detecting a target polynucleotide of claim 38 wherein [the target polynucleotide is amplified with a polymerase] said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

Of the claims 41-59 introduced in the Preliminary Amendment of March 8, 2000, claims 41, 44, 47, and 53-59 have been canceled without prejudice. Of the remaining claims, please cancel claim 45 (which was dependent on a canceled claim) without prejudice. Please amend claims 42, 43, 46, 48-52 as follows: (the attached Appendix I identifies the changes from the claims as introduced):

42. The amplification method of claim 1 wherein said amplifying *in vitro* is linear or exponential.

43. The amplification method of claim 42 wherein said amplifying *in vitro* is exponential.

46. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

48. The detection method of claim 7 wherein said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 48 wherein said amplifying *in vitro* is exponential.

50. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

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51. The detection method of claim 50 wherein said amplifying *in vitro* is linear or exponential.

52. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

The claims 60-63 added by the Preliminary Amendment of July 16, 2001, have already been canceled without prejudice.

Of the claims 64-82 added in the Amendment of March 8, 2002, please cancel claims 68, 69, and 76-82 without prejudice. Please amend claims 64-67 and 71-72 as follows (the attached Appendix I identifies the changes from the claims as introduced):

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

Please add new claims 83-86 as follows:

83. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

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84. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

85. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

86. The method of claim 85 wherein the sample is a clinical sample.

REMARKS

The Patent Owner and its representatives wish to express their appreciation to each of the PTO representatives that have participated in the examination of this application. Specifically, the Patent Owner thanks Supervisory Primary Examiner Gary Jones, Special Programs Examiner Julie Burke, Primary Examiner Carla Myers, Primary Examiner Lisa Arthur, and particularly, Examiner Dianna Johannsen.

The amendments presented here reflect the draft proposed amendment of March 28, 2002, as discussed and modified during the interview of April 2, 2002, and as reflected in the Interview Summary forwarded by facsimile on April 3, 2002. After these amendments, claims 1-19, 27-40, 42, 43, 46, 48-52, 64-67, 70-75, and 83-86 will be pending. To assist the Office, a clean copy of these pending claims is attached in Appendix II.

As noted during the Interview, the submission of additional claim amendments would necessitate the filing of a supplemental oath/declaration to satisfy the requirements of 35 U.S.C. 251. Accordingly, the Patent Owner is submitting herewith a second supplemental reissue declaration by its representative Norval Galloway that states that:

> All errors which are being corrected in the present reissue application up to the time of the filing of this second supplemental oath/declaration, and which are not covered by a prior oath/declaration submitted in this application, arose without any deceptive intent on the part of the Patent Owner and of the inventors.

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For the foregoing reasons, the Patent Owner respectfully submits that the claims are in condition for allowance and earnestly requests prompt notification to this effect.

If there are any fees due in connection with the filing of this Amendment not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

DRAFT

By:_____
Jean Burke Fordis
Reg. No. 32,984

Dated: April __, 2002
30209

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Appendix I showing amendments to claims added during prosecution

42. The amplification method of claim [41] 1 wherein said amplifying *in vitro* [the amplification] is linear or exponential.

43. The amplification method of claim 42 wherein said amplifying *in vitro* [the amplification] is exponential.

46. The amplification method of claim [41] 1 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

48. The detection method of claim [47] 7 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 48 wherein [the amplification] said amplifying *in vitro* is exponential.

50. The detection method of claim [47] 7 wherein said amplifying *in* vitro comprises amplifying said [the] separated target polynucleotide [is amplified] with [a polymerase and] at least one oligonucleotide primer.

51. The detection method of claim 50 wherein [the amplification] said amplifying *in vitro* is linear or exponential.

52. The detection method of claim [47] 7 wherein [the target polynucleotide is amplified with more than one polymerase] said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

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67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] non-specifically [with random primers].

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said [the] separated target polynucleotide [is amplified] specifically [with specially tailored primers].

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Appendix II with clean copy of pending claims

1. A method for amplifying a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide; and

(c) amplifying *in vitro* the separated target polynucleotide of (b).

2. The method of claim 1 wherein the first support is retrievable.

3. The method of claim 1 wherein the first support includes a probe which binds with the target polynucleotide.

4. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

5. The method of claim 4 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

6. The method of claim 4 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

7. A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

(c) amplifying *in vitro* the separated target polynucleotide of (b), thereby producing an amplified target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide of (c) as indicative of the presence of the target polynucleotide in said sample.

8. The method of claim 7 wherein the first support is retrievable.

9. The method of claim 8 wherein the first support includes a probe which binds with the

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target polynucleotide.

10. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

11. The method of claim 10 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

12. The method of claim 11 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

13. The method of claim 7 wherein the amplified target polynucleotide is contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. The method of claim 7 wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

15. The method of claim 7 wherein the amplified target polynucleotide is contacted with a second support which binds to the amplified target polynucleotide.

16. The method of claim 15 wherein the second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

17. The method of claim 16 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with a polymerase.

18. The method of claim 17 wherein the separated target polynucleotide is a DNA polynucleotide and the polymerase is a DNA polymerase.

19. A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample, thereby producing a separated target polynucleotide;

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(c) amplifying *in vitro* the separated target polynucleotide of (b) with a DNA polymerase, thereby producing an amplified target polynucleotide;

(d) contacting the amplified target polynucleotide of (c) with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and

(e) detecting the presence of the labeled probe as indicative of the presence of the target polynucleotide in said sample.

[claims 20-26 canceled]

27. A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium.

28. A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

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(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide in the probe-target complex present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

29. The method of detecting a target polynucleotide of claim 28 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

30. The method for detecting a target polynucleotide of claim 29 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

31. The method for detecting a target polynucleotide of claim 30 wherein the polymerase is a DNA polymerase.

32. The method for amplifying a target polynucleotide of claim 27 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

33. The method for amplifying a target polynucleotide of claim 32 wherein the polymerase is a DNA polymerase.

34. A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

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(e) substantially separating the support and bound probe from the second medium; and

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. The method for amplifying a target polynucleotide of claim 34 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

36. The method for amplifying a target polynucleotide of claim 35 wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase.

37. The method for amplifying a target polynucleotide of claim 36 wherein the polymerase is a DNA polymerase.

38. A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide of (c) into the second medium;

(e) substantially separating the support and bound probe form the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium, thereby producing an amplified target polynucleotide; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

39. The method for detecting a target polynucleotide of claim 38 wherein said amplifying *in vitro* comprises amplifying said target polynucleotide with a polymerase.

40. The method for detecting a target polynucleotide of claim 39 wherein the polymerase is a DNA polymerase.

[claim 41 canceled]

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42. The amplification method of claim 1 wherein said amplifying *in vitro* is linear or exponential.

43. The amplification method of claim 42 wherein said amplifying *in vitro* is exponential.

[claims 44-45 canceled]

46. The amplification method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

[claim 47 canceled]

48. The detection method of claim 7 wherein said amplifying *in vitro* is linear or exponential.

49. The detection method of claim 48 wherein said amplifying *in vitro* is exponential.

50. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with at least one oligonucleotide primer.

51. The detection method of claim 50 wherein said amplifying *in vitro* is linear or exponential.

52. The detection method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with more than one polymerase.

[claims 53-63 canceled]

64. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

65. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

66. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

67. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

[claims 68-69 canceled]

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70. The method of claim 9 wherein the probe first binds with the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

71. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide non-specifically.

72. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide specifically.

73. The method of claim 72 wherein the sample is a clinical sample.

74. The method of claim 73 wherein the probe comprises a nucleotide sequence specific to a complementary nucleotide sequence in the target polynucleotide and a homopolymeric tail sequence.

75. The method of claim 74 wherein the support comprises a homopolymeric tail complementary to the homopolymeric tail of the probe.

[claims 76-82 canceled]

83. The method of claim 1 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

84. The method of claim 7 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

85. The method of claim 70 wherein said amplifying *in vitro* comprises amplifying said separated target polynucleotide with specially tailored primers.

86. The method of claim 85 wherein the sample is a clinical sample.

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